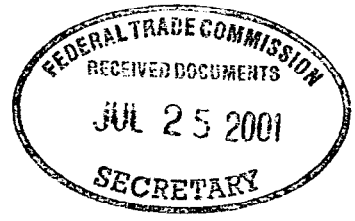
UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION



In the Matter of	
Schering-Plough Corporation, a corporation,	
Upsher-Smith Laboratories, Inc., a corporation,	**Docket No. 9297**
	PUBLIC
and	
American Home Products Corporation, a corporation.	

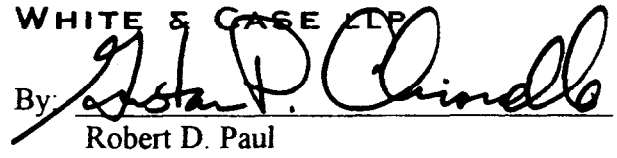
UPSHER-SMITH'S MOTION FOR AN ORDER AUTHORIZING THE SECRETARY OF THE COMMISSION TO ISSUE A SUBPOENA *DUCES TECUM* TO THE FOOD AND DRUG ADMINISTRATION

Pursuant to Rule 3.36 of the Commission's Rules of Practice, Upsher-Smith hereby moves for an Order authorizing the Secretary of the Commission to issue a subpoena *duces tecum* to the Food and Drug Administration. The accompanying memorandum attaches a description of the material to be produced pursuant to the proposed subpoena. Complaint Counsel does not oppose this motion.

Dated: July 25, 2001

Respectfully submitted,

WHITE & CASE LLP

By: 

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Attorneys for Upsher-Smith Laboratories, Inc.

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of	)	
Schering-Plough Corporation, a corporation,	)	
Upsher-Smith Laboratories, Inc., a corporation,	)	**Docket No. 9297**
and	)	**PUBLIC**
American Home Products Corporation, a corporation.	)	

UPSHER-SMITH'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR AN ORDER AUTHORIZING THE SECRETARY OF THE COMMISSION TO ISSUE A SUBPOENA *DUCES TECUM* TO THE FOOD AND DRUG ADMINISTRATION

As explained below, Upsher-Smith seeks to serve a narrowly focused subpoena *duces tecum* on the Food and Drug Administration to discover certain facts critical to Upsher-Smith's defense of this proceeding. Complaint Counsel does not oppose this motion.

BACKGROUND

The Commission's Complaint alleges that entry has been restricted for the manufacture and sale of all potassium chloride supplements, and that the FDA's grant of 180-day exclusivity to Upsher-Smith has blocked entry of other versions K-Dur 20. (Complaint ¶¶ 21, 28, 29 47, 50, 63). In support of these allegations, the Complaint identifies only one company that has filed an ANDA for a generic version of K-Dur 20. That company is Andrx, whose ANDA evidently has not been tentatively approved by the FDA. (Complaint ¶ 61). In order to fully respond to the Complaint's allegations, Upsher-Smith seeks to discover exactly which, if any, other companies

have applied to the FDA for NDAs and ANDAs to market generic versions of K-Dur 20 or similar products. Because the identity of NDA and ANDA filers is kept confidential by the FDA until the applications are approved or tentatively approved, a subpoena *duces tecum* is necessary to obtain this information. Accordingly, Upsher-Smith seeks such a subpoena requiring the FDA to produce documents sufficient to identify the NDA and ANDA filers. Upsher-Smith will then seek to discover from the alleged filers themselves whether or not they have actually been blocked from competing by the FDA's grant of 180-day exclusivity to Upsher-Smith.

ARGUMENT

I. The Requested Subpoena *Duces Tecum* Because Satisfies All Requirements Under the Applicable Commission Rules of Practice.

Rule 3.36(b) of the Commission's Rules of Practice requires that a party seeking issuance of a subpoena for records of governmental agencies make a specific showing that:

> "(1) The material sought is reasonable in scope;
>
> (2) If for the purposes of discovery, the material falls within the limits of discovery under §3.31(c)(1), or, if an adjudicative hearing, the material is reasonably relevant;
>
> (3) The information or material sought cannot reasonably be obtained by other means; and
>
> (4) With respect to subpoenas to be served in a foreign country, the party seeking discovery has a good faith believe that the discovery requested would be permitted by treaty, law, custom or practice in the country from which the discovery is sought and that any additional procedural requirements have been or will be met before the subpoena is served."

16 C.F.R. § 3.36(b). If these requirements are satisfied, the Court may authorize the Secretary of the Commission to issue the requested subpoena *duces tecum* under Rule 3.31.

A. The Material Sought In This Motion Is Reasonable in Scope.

Upsher-Smith seeks only copies of the forms submitted to the FDA by NDA and ANDA filers for potassium chloride since 1995. (See Attachment A). This two-page form contains basic company identification data and information about the drug for which the company is seeking FDA approval. (See Exhibit B, Form FDA 356h). While many NDA and ANDA filings are accompanied by volumes of attachments necessary for the FDA's review of testing results, Upsher-Smith seeks only copies of Form FDA 356h and not the attachments.

Upsher-Smith does not believe that the subpoena would be burdensome to the FDA. Indeed, Upsher-Smith believes that the information concerning NDA and ANDA filers of potassium chloride products is readily available and kept by the FDA as information accessible during the ordinary course of business.

Given the importance of this information to this matter, the relative burden on the FDA is minimal. The specification in the subpoena is for a limited set of material, the volume of which is expected to be relatively small and kept in the ordinary course of business. Moreover, the information supplied by the FDA is expected to lead to the discovery of additional information critical to the prompt and efficient resolution of this adjudicative proceeding. Again, Upsher-Smith only seeks minimal, but essential, information contained in the responsive NDA and ANDA files in an effort to reduce the burden imposed on the FDA

B. The Material Sought Falls Within the Limits of Discovery.

Rule 3.31(c)(1), which addresses the general rules and limitations on the scope of discovery, states in pertinent part :

> "Parties may obtain discovery to the extent that it may be reasonably expected to yield information relevant to the allegations of the complaint, to the proposed relief, or to the defenses of any respondent."

16 C.F.R. 3.31(c)(1).

To respond fully to the Complaint's allegations, Upsher-Smith needs information from the FDA on exactly who has sought to compete in the manufacture and sale of potassium chloride supplements during all relevant times. Upsher-Smith needs copies of NDA and ANDA forms to identify who may have evidence that other companies were not barred from entering the market. Once the NDA and ANDA filers have been identified, Upsher-Smith anticipates serving additional subpoenas on the filers. Accordingly, Upsher-Smith expects that information obtained from the FDA subpoena will clarify the condition of the potassium chloride market and specifically address the allegations that competitors were barred from entry.

C. **The Material Sought Cannot Be Obtained By Other Means.**

The FDA does not publicly disclose the identity of NDA and ANDA filers until the FDA tentatively or finally approves their applications. Because the FDA keeps this material confidential, a subpoena is necessary to obtain the filers' identities.[1]

Other than serving a subpoena upon the FDA, Upsher-Smith's only alternative to obtain this information is to guess, and accordingly serve subpoenas on the more than 150 known pharmaceutical companies that do business in the United States to determine if any had made a potassium chloride NDA or ANDA filing with the FDA since 1995. This exercise obviously

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[1] Upsher-Smith cannot obtain this information from respondent Schering-Plough. The Complaint alleges that the relevant product markets include the "manufacture and sale of all potassium chloride supplements approved by the FDA." (Complaint ¶ 21). Schering-Plough would only receive Paragraph IV notification from ANDA filers seeking to replicate its specific patented forms of potassium chloride. However, because the Complaint alleges a relevant market broader than the specific Schering-Plough patents, only the FDA has information about all NDA and ANDA filers for the alleged relevant markets.

would impose an enormous cost of time and money on Upsher-Smith and the parties subpoenaed. Moreover, such a method of discovery would not yield a certain result because there is a probability that some potential potassium chloride NDA and ANDA filers would still be unidentified. Consequently, this proposed FDA subpoena is the fastest, most efficient method for Upsher-Smith to locate the complete set of potential market competitors.

While the FDA naturally has an interest in ensuring that the identity of NDA and ANDA filers remain confidential, any concern about maintaining confidentiality is alleviated by the provisions of the Protective Order entered in this case. As the terms of the Protective Order indicate, the FDA need only clearly mark the documents as "Restricted Confidential, Attorney Eyes Only" to ensure that the information will continue to be treated confidentially. (Protective Order Governing Discovery Material, p. 6).

D. Because This Subpoena Does Not Involve Service In Any Foreign State, Rule 3.36(b)(4) Does Not Apply.

Because this subpoena does not involve service in a foreign jurisdiction, the Court does not need to consider any applicable treaty, law, custom or practice in the country from which the discovery is sought.

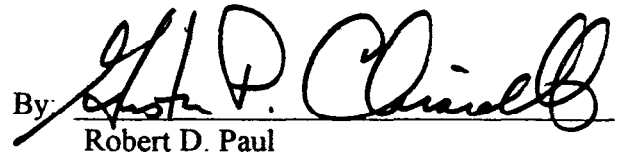
CONCLUSION

For the reasons stated above, the Court should grant Upsher-Smith's Motion and authorize the Secretary of the Commission to issue a subpoena *duces tecum* to the FDA.

Dated: July 25, 2001

Respectfully submitted,

WHITE & CASE LLP

By: 

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Telephone: (202) 626-3600
Facsimile: (202) 639-9355

Attorneys for Upsher-Smith Laboratories, Inc.

MATERIAL TO BE PRODUCED

1. A copy of each New Drug Application and Abbreviated New Drug Application submitted after January 1, 1995 on which the "Chemical/BioChemical/Blood Product Name" is identified as POTASSIUM CHLORIDE. (This subpoena *duces tecum* seeks the completed Application form (Form 356h or equivalent), but does not seek any attachments or other materials accompanying the Application.)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: March 31, 2003
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
TELEPHONE NO. *(Include Area Code)*	FACSIMILE (FAX) Number *(Include Area Code)*
APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued)*:	AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER *(If previously issued)*

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*	PROPRIETARY NAME *(trade name)* IF ANY
CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*	CODE NAME *(If any)*

DOSAGE FORM:	STRENGTHS:	ROUTE OF ADMINISTRATION:

(PROPOSED) INDICATION(S) FOR USE:

APPLICATION INFORMATION

APPLICATION TYPE *(check one)* ☐ NEW DRUG APPLICATION (21 CFR 314.50) ☐ ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94) ☐ BIOLOGICS LICENSE APPLICATION (21 CFR Part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☐ 505 (b)(1) ☐ 505 (b)(2)

IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION
Name of Drug Holder of Approved Application

TYPE OF SUBMISSION *(check one)* ☐ ORIGINAL APPLICATION ☐ AMENDMENT TO A PENDING APPLICATION ☐ RESUBMISSION ☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ EFFICACY SUPPLEMENT ☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☐ OTHER

IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION: _____

IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY ☐ CBE ☐ CBE-30 ☐ Prior Approval (PA)

REASON FOR SUBMISSION

PROPOSED MARKETING STATUS *(check one)* ☐ PRESCRIPTION PRODUCT (Rx) ☐ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED _____ THIS APPLICATION IS ☐ PAPER ☐ PAPER AND ELECTRONIC ☐ ELECTRONIC

ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the Application.)
Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

This application contains the following items: *(Check all that apply)*	
	1. Index
	2. Labeling *(check one)* ☐ Draft Labeling ☐ Final Printed Labeling
	3. Summary (21 CFR 314.50 (c))
	4. Chemistry section
	A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)
	B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request)
	C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)
	5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)
	6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)
	7. Clinical Microbiology (e.g., 21 CFR 314.50(d)(4))
	8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)
	9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)
	10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)
	11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)
	12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)
	13. Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))
	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A))
	15. Establishment description (21 CFR Part 600, if applicable)
	16. Debarment certification (FD&C Act 306 (k)(1))
	17. Field copy certification (21 CFR 314.50 (l)(3))
	18. User Fee Cover Sheet (Form FDA 3397)
	19. Financial Information (21 CFR Part 54)
	20. OTHER *(Specify)*

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act Section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.

Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE

ADDRESS *(Street, City, State, and ZIP Code)*	Telephone Number
	( )

Public reporting burden for this collection of information is estimated to average 24 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
CBER, HFM-99
1401 Rockville Pike
Rockville, MD 20852-1448

Food and Drug Administration
CDER, HFD-94
12420 Parklawn Dr., Room 3046
Rockville, MD 20852

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

FORM FDA 356h (4/00)

INSTRUCTIONS FOR FILLING OUT FORM FDA 356h

APPLICANT INFORMATION This section should include the name, street address, telephone and facsimile numbers of the legal person or entity submitting the application in the appropriate areas. Note that, in the case of biological products, this is the name of the legal entity or person to whom the license will be issued. The name, street address and telephone number of the legal person or entity authorized to represent a non-U.S. Applicant should be entered in the indicated area. Only one person should sign the form.

PRODUCT DESCRIPTION This section should include all of the information necessary to identify the product that is the subject of this submission. For new applications, the proposed indication should be given. For supplements to an approved application, please give the approved indications for use.

APPLICATION INFORMATION If this submission is an ANDA or 505(b)(2), this section should include the name of the approved drug that is the basis of the application and identify the holder of the approved application in the indicated areas.

TYPE OF SUBMISSION should be indicated by checking the appropriate box:

Original Application = a complete new application that has never before been submitted;

Amendment to a Pending Application = all submissions to pending original applications, or pending supplements to approved applications, including responses to Information Request Letters;

Resubmission = a complete response to an action letter, or submission of an application that has been the subject of a withdrawal or a refusal to file action;

Presubmission = information submitted prior to the submission of a complete new application;

Annual Report = periodic reports for licensed biological products (for NDAs Form FDA-2252 should be used as required in 21 CFR 314.81 (b)(2));

Establishment Description Supplement = supplements to the information contained in the Establishment Description section (#15) for biological products;

Efficacy Supplement = submissions for such changes as a new indication or dosage regimen for an approved product, a comparative efficacy claim naming another product, or a significant alteration in the patient population; e.g., prescription to Over-The-Counter switch;

Labeling Supplement = all label change supplements required under 21 CFR 314.70 and 21 CFR 601.12 that do not qualify as efficacy supplements;

Chemistry, Manufacturing and Controls Supplement = manufacturing change supplement submissions as provided in 21 CFR 314.70, 21 CFR 314.71, 21 CFR 314.72 and 21 CFR 601.12;

Other = any submission that does not fit in one of the other categories (e.g., Phase IV response). If this box is checked the type of submission can be explained in the **REASON FOR SUBMISSION** block.

Submission of Partial Application Letter date of agreement to partial submission should be provided. Also, provide copy of scheduled plan.

CBE "Supplement-Changes Being Effected" supplement submission for certain moderate changes for which distribution can occur when FDA receives the supplement as provided in 21 CFR 314.70 and 21 CFR 601.12.

CBE-30 "Supplement-Changes Being Effected in 30 Days" supplement submission for certain moderate changes for which FDA receives at least 30 days before the distribution of the product made using the change as provided in 21 CFR 314.70 and 21 CFR 601.12.

Prior Approval (PA) "Prior Approval Supplements" supplement submission for a major change for which distribution of the product made using the change cannot occur prior to FDA approval as provided in 21 CFR 314.70 and 21 CFR 601.12.

REASON FOR SUBMISSION This section should contain a brief explanation of the submission, e.g., "manufacturing change from roller bottle to cell factory" or "response to Information Request Letter of 1/9/97" or "Pediatric exclusivity determination request" or "to satisfy a subpart H postmarketing commitment".

NUMBER OF VOLUMES SUBMITTED Please enter the number of volumes, including and identifying electronic media, contained in the archival copy of this submission.

This application is
☐ Paper ☐ Paper and Electronic ☐ Electronic
Please check the appropriate box to indicate whether this submission contains only paper, both paper and electronic media, or only electronic media.

ESTABLISHMENT INFORMATION This section should include information on the locations of all manufacturing, packaging and control sites for both drug substance and drug product. If continuation sheets are used, please indicate where in the submission they may be found. For each site please include the name, address, telephone number, registration number (Central File Number), Drug Master File number, and the name of a contact at the site. The manufacturing steps and/or type of testing (e.g. final dosage form, stability testing) conducted at the site should also be included. Please indicate whether the site is ready for inspection or, if not, when it will be ready. Please note that, when applicable, the complete establishment description is requested under item 15.

CROSS REFERENCES This section should contain a list of all License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs and DMFs that are referenced in the current application.

Items 1 through 20 on the reverse side of the form constitute a check list that should be used to indicate the types of information contained within a particular submission. Please check all that apply. The numbering of the items on the checklist is not intended to specify a particular order for the inclusion of those sections into the submission. The applicant may include sections in any order, but the location of those sections within the submission should be clearly indicated in the Index. It is therefore recommended that, particularly for large submissions, the Index immediately follows the Form FDA 356h and, if applicable, the User Fee Cover Sheet (Form FDA 3397).

The CFR references are provided for most items in order to indicate what type of information should be submitted in each section. For further information, the applicant may consult the guidance documents that are available from the Agency.

Signature The form must be signed and dated. Ordinarily only one person should sign the form, i.e., the applicant, or the applicant's attorney, agent, or other authorized official. However, if the person signing the application does not reside or have a place of business within the United States, the application should be countersigned by an attorney, agent, or other authorized official who resides or maintains a place of business within the United States.

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of	)	
Schering-Plough Corporation, a corporation,	)	
Upsher-Smith Laboratories, Inc., a corporation,	)	**Docket No. 9297**
	)	**PUBLIC**
and	)	
American Home Products Corporation, a corporation.	)	

ORDER

Upon consideration of Upsher-Smith's Motion For An Order Authorizing The Secretary of the Commission To Issue A Subpoena *Duces Tecum* to the Food and Drug Administration and the record as a whole, it is hereby ORDERED that the Consent Motion is GRANTED. In accordance with Commission Rule 3.36(c), Upsher-Smith may forward to the Secretary a request, with this Order attached, for an authorized subpoena *duces tecum* to be served on the United States Food and Drug Administration.

Dated: August ___, 2001
Washington, DC

D. Michael Chappell
Administrative Law Judge

CERTIFICATE OF SERVICE

I, J. Carlos Alarcon, hereby certify that on July 25, 2001, I caused a copy of Upsher-Smith Consent Motion For An Order Authorizing the Secretary of the Commission to Issue a Subpoena *Duces Tecum* To the United States Food and Drug Administration to be served upon the following persons by courier delivery.

The Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Karen G. Bokat
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Laura S. Shores
Howrey Simon Arnold & White
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Cathy Hoffman
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Thurman Arnold Building
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J. Carlos Alarcon